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EXAMINER	
HOPKINS, CHRISTINE D	
ART UNIT	PAPER NUMBER
3735	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	03/26/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/622,129	LICHTENSTEIN, SAMUEL	
	Examiner	Art Unit	
	Christine D. Hopkins	3735	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *11 December 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-102* is/are pending in the application.

4a) Of the above claim(s) *18,19,50,51,87 and 88* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-17,20-49,52-86 and 89-102* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restriction

1. Claims 18, 50 and 87-88 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 11 December 2006. It is further noted that claims 19 and 51 are withdrawn based on their dependency upon withdrawn claims 18 and 50, respectively.

Claim Objections

2. Claim 14 objected to because of the following informalities: at line 1 of claim 14, "the method of claim 1" should apparently ready --the method of claim 13--. Appropriate correction is required.

3. The numbering of claims is not in accordance with 37 CFR 1.126 which requires the original numbering of the claims to be preserved throughout the prosecution. When claims are canceled, the remaining claims must not be renumbered. When new claims are presented, they must be numbered consecutively beginning with the number next following the highest numbered claims previously presented (whether entered or not). Misnumbered claims 98 (duplicated) -101 have been renumbered 99-102.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claim 68 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 68 at line 2 recites the limitation "the attachment tool." There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

7. Claims 1-15, 17, 23-30, 32-47, 49, 55-62, 64-84, 86, 92-100 and 102 are rejected under 35 U.S.C. 102(e) as being anticipated by Taylor et al. (U.S. Pub. No. 2002/0169360). Taylor et al. (hereinafter Taylor) disclose methods and devices for assisting cardiac function of the heart, specifically treatment of the left ventricle. Regarding claims 1-3, 6-7 and 10, Taylor teaches a method whereby a displacement device **111** delivers an expandable element **113**, moveable between a collapsed and expanded configuration, into the left ventricle. The expandable element is expanded after placement within the ventricle, forming a circumferential attachment, separating a blood-flow and non-blood flow side, noted by Taylor as "dead space" [0086] (also see Figs. 12A-12B). An end cap **117** secures the element **113** to the wall of the ventricle. In

view of claim 4, the element may also be introduced through the aorta and into the left ventricle [0089]. Regarding claim 5, the advancing step also being carried out through the ventricular walls [0058].

In view of claims 8-9 and 30, the expandable and inflatable characteristics of the expandable element allow it to be shaped to a desired geometry of the left ventricle [0088]. The outer surface of the expandable element **113** is generally convex and has an apex in the expanded position (see Fig. 12B).

Regarding claims 11 and 12, the volume displacement device **111**, in conjunction with the inflation device **115**, act to evacuate blood from the non-blood flow side following the expanding step. Since the expandable element works to reduce blood volume of the ventricle, evacuation of blood moves the expandable element into contact with the left ventricle [0086].

With respect to claims 13 and 14, a tool **115** is introduced into the chest, engages the heart, and secures the expandable element in the left ventricle, which constitutes an isolated portion of the left ventricle, by increasing the volume of the expandable element and thus securing the element to the walls of the left ventricle (see Fig. 13).

Regarding claim 15, an "anchor" or suture may be driven through the ventricle in order to fix the expandable element **113** to the ventricle [0089].

In view of claims 17, 23, and 27 the heart volume is "displaced" by initially inflating the expandable device, which occurs prior to it being effectively secured upon complete inflation, to the desired geometry. The heart is thus held in such a displaced

condition upon terminating the introduction of more fluid [0086]. Regarding claim 24, such displacement is also interpreted as twisting since the expandable device encircles and subsequently displaces portions of the heart tissue.

With respect to claim 25, a tool **115**, which acts to displace the heart, may be left surgically accessible to allow future adjustments whereby the inflation tube is maintained subcutaneously such that an incision would allow access to the tool, and thus to the heart [0088]. Regarding claim 26, an "anchoring device" or suture may be driven through the ventricle in order to fix the expandable element **113** to the heart [0089].

Referring to claims 28 and 29, the expandable element **113** may be pre-shaped to more closely approximate the ventricular geometry of the patient [0086].

Regarding claim 32, Taylor teaches that the expandable member **113** may be left within the patient allowing the surgeon to, at a subsequent time, access the member and adjust the device through expansion or contraction with tool **115** [0088].

Referring to claims 33, 38-39 and 42, Taylor teaches a method whereby a displacement device **111** delivers an expandable element **113**, moveable between a collapsed and expanded configuration, into the left ventricle. The expandable element is expanded after placement within the ventricle, forming a circumferential attachment, separating a blood-flow and non-blood flow side (see Figs. 12A-12B). An end cap **117** secures the element **113** to the wall of the ventricle. Installation of the device is done through the apex of the heart, thus being at a position below the papillary muscles. Furthermore, an end cap enables the securing step, which is also at a position on the

apex, thus being below the papillary muscles as recited in claims 34 and 35 (see Figs. 12A-B and 13).

In view of claim 36, the element may also be introduced through the aorta and into the left ventricle [0089]. Regarding claim 37, the advancing step is also being carried out through the ventricular walls [0058].

In view of claims 40-41, the expandable and inflatable characteristics of the expandable element allow it to be shaped to a desired geometry of the left ventricle [0088]. The outer surface of the expandable element **113** is generally convex and has an apex in the expanded position (see Fig. 12B).

Regarding claims 43 and 44, the volume displacement device **111**, in conjunction with the inflation device **115**, act to evacuate blood from the non-blood flow side following the expanding step. Since the expandable element works to reduce blood volume of the ventricle, evacuation of blood moves the expandable element into contact with the left ventricle [0086].

With respect to claims 45 and 46, a tool **115** is introduced into the chest, engages the heart, and secures the expandable element in the left ventricle, which constitutes an isolated portion of the left ventricle, by increasing the volume of the expandable element and thus securing the element to the walls of the left ventricle (see Fig. 13).

Regarding claim 47, an "anchor" or suture may be driven through the ventricle in order to fix the expandable element **113** to the ventricle [0089].

In view of claims 49, 55, and 59 the heart volume is "displaced" by initially inflating the expandable device, which occurs prior to it being effectively secured upon complete inflation to the desired geometry. The heart is thus held in such a displaced condition upon terminating the introduction of more fluid [0086]. Regarding claim 56, such displacement is also interpreted as twisting since the expandable device encircles and subsequently displaces portions of the heart tissue.

With respect to claim 57, a tool **115**, which acts to displace the heart, may be left surgically accessible to allow future adjustments whereby the inflation tube is maintained subcutaneously such that an incision would allow access to the tool, and thus to the heart [0088]. Regarding claim 58, an "anchoring device" or suture may be driven through the ventricle in order to fix the expandable element **113** to the heart [0089].

Referring to claims 60 and 61, the expandable element **113** may be pre-shaped to more closely approximate the ventricular geometry of the patient [0086]. The outer surface of the expandable element **113** is generally convex and has an apex in the expanded position, in accordance with claim 62 (see Fig. 12B).

Regarding claim 64, Taylor teaches that the expandable member **113** may be left within the patient allowing the surgeon to, at a subsequent time, access the member and adjust the device through expansion or contraction with tool **115** [0088].

In view of claims 65 and 66, Taylor discloses a displacement device **111** that delivers a "sealing element" **113** to the left ventricle. Element **113** has a generally convex outer surface, an apex and a circumferential sealing portion (interpreted as the

circumference of the "sealing element") which is configured to "seal" against the internal wall of the left ventricle (see Figs. 12A-12B and 13). The expandable and inflatable characteristics of the "sealing element" allow it to be shaped to a desired geometry of the left ventricle [0088].

With respect to claim 67, an attachment tool **115**, positioned outside, and configured to engage the heart (see Fig. 13), attaches at least a part of the element **113** to the wall of the left ventricle upon introduction and inflation of the element.

Regarding claim 68, and in view of its lack of antecedent basis, an "anchoring device" or suture may be driven through the ventricle in order to fix the element **113** to the heart [0089].

Referring to claims 69-72, Taylor teaches a method whereby a displacement device **111** delivers an expandable element **113**, moveable between a collapsed and expanded configuration, in a collapsed state into the left ventricle. The expandable element is expanded after placement within the ventricle. Adjustment of its size by inflation secures its to the walls of the ventricle and separates a blood-flow and non-blood flow side (see Figs. 12A-12B). The volume of the non-blood flow side or "dead space," as taught by Taylor, is thus maintained and reduced [0086]. At a later point, as the surgeon sees fit, the size of the expandable element may be reduced, thus evacuating blood from the non-blood flow side. In view of claims 73-75, the reducing step is further interpreted as the step at which the element forms a "seal" against the wall of the ventricle. Expanding the element at such a point forms a seal and prevents blood from passing to the non-blood flow side or the area known as "dead space."

The securing step includes a point of the ventricle which contacts the expandable element. Since the area at the apex also contacts the element, it is interpreted to be below the papillary muscle, in accordance with claims 76 and 77. Regarding claim 78, the advancing step is carried out through the ventricular walls [0058].

In view of claims 79 and 80, the expandable and inflatable characteristics of the expandable element allow it to be shaped to a desired geometry of the left ventricle [0088]. The outer surface of the expandable element **113** is generally convex and has an apex in the expanded position (see Fig. 12B). Referring to claim 81, since the expandable element works to reduce blood volume of the ventricle, evacuation of blood upon adjustment of the element moves the element into contact with the left ventricle [0086].

With respect to claims 82 and 83, a tool **115** is introduced into the chest, engages the heart, and secures the expandable element in the left ventricle, which constitutes an isolated portion of the left ventricle, by increasing the volume of the expandable element and thus securing the element to the walls of the left ventricle (see Fig. 13).

Regarding claim 84, an "anchor" or suture may be driven through the ventricle in order to fix the expandable element **113** to the ventricle [0089].

In view of claims 86 and 92, the heart volume is "displaced" by initially inflating the expandable device, which occurs prior to it being effectively secured upon complete inflation to the desired geometry. The heart is thus held in such a displaced condition upon terminating the introduction of more fluid [0086]. Regarding claim 93, such

displacement is also interpreted as twisting since the expandable device encircles and subsequently displaces portions of the heart tissue.

With respect to claim 94, a tool **115**, which acts to displace the heart, may be left surgically accessible to allow future adjustments whereby the inflation tube is maintained subcutaneously such that an incision would allow access to the tool, and thus to the heart [0088]. Referring to claim 95, the expandable element **113** may be pre-shaped to more closely approximate the ventricular geometry of the patient prior to delivery 0086].

Regarding claim 96, Taylor teaches that the expandable member **113** may be left within the patient allowing the surgeon to, at a subsequent time, access the member and adjust the device through expansion or contraction with tool **115** [0088].

In view of claims 97 and 99, Taylor discloses a displacement device **111** that delivers a "sealing element" **113** to the left ventricle. Element **113** has a generally convex outer surface, an apex and a circumferential sealing portion (interpreted as the circumference of the "sealing element") which is configured to "seal" against the internal wall of the left ventricle (see Figs. 12A-12B and 13). The expandable and inflatable characteristics of the "sealing element" allow it to be shaped to a desired geometry of the left ventricle [0088], thus preventing blood passing into the "dead space" or "non-blood flow side" and reducing pressure [0086].

Regarding claims 98 and 100, an attachment device such as a staple or suture mechanically attaches the "sealing" element **113** to the heart [0089].

Referring to claim 102, since the element of Taylor acts to decrease the "dead space" within a diseased heart, the element is interpreted to isolate a septal defect being that the "dead space" is isolated from the efficiently functioning portion of the heart [0086].

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

9. Claims 16, 48, 85 and 101 are rejected under 35 U.S.C. 103(a) as being unpatentable over Taylor et al. (U.S. Pub. No. 2002/0169360). Regarding claims 16, 48 and 85, Taylor teaches the step of securing an expandable element to the wall of the left ventricle with a suture, staple, or other fastening mechanism [0089]. However, Taylor does not disclose the securing step being performed with an energy source. Applicant has not disclosed that securing the element to the wall of the ventricle with an energy source solves any stated problem or is for any particular purpose. Moreover, it appears that the securing step disclosed by Taylor, or Applicant's invention, would perform equally well with the fastening step presented by Taylor.

Accordingly, it would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to have modified Taylor such that the securing step included the activation of an energy source because such a modification would

have been considered a mere design consideration which fails to patentably distinguish over Taylor since both the invention of Taylor and that of Applicant aim to secure the expandable element to the wall of the left ventricle.

Regarding claim 101, Taylor teaches a mechanical attachment for securing an element to the heart whereby a suture, staple, or other such mechanism connects the element to the heart [0089]. However, Taylor does not disclose such an attachment device delivering energy to secure the element to the heart. Applicant has not disclosed that securing the element to the wall of the ventricle with an energy source solves any stated problem or is for any particular purpose. Moreover, it appears that the attachment mechanism disclosed by Taylor, or Applicant's invention, would perform equally well with the fastening mechanism presented by Taylor.

Accordingly, it would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to have modified Taylor such that an attachment device delivered energy to the sealing element to attach it to the heart because such a modification would have been considered a mere design consideration which fails to patentably distinguish over the prior art since both the invention of Taylor and that of Applicant aim to secure the expandable element to the wall of the left ventricle.

10. Claims 20-22, 52-54 and 89-91 are rejected under 35 U.S.C. 103(a) as being unpatentable over Taylor et al. (U.S. Pub. No. 2002/0169360) in view of Jang (U.S. Patent No. 6,287,321). Taylor discloses the invention as claimed, see rejection supra; however Taylor fails to disclose that the delivery device has a filter. Jang discloses a delivery device having an expandable member and filter utilized during cardiac surgery.

Regarding claims 20-22, 52-54 and 89-91, Jang teaches a delivery device **1** having an expandable filter **10**, being moveable between collapsed and expanded positions (col. 3, lines 12-18). The filter is expanded following introduction through the patient in an effort to trap embolic material (col. 3, lines 49-52). Such a device may be introduced into the left ventricular chamber (col. 4, lines 39-43). Moreover, Taylor teaches the prevention of thrombosis, but does not explicitly disclose the use of an expandable filter [0059]. Therefore, at the time of the invention it would have been obvious to one having ordinary skill in the art to have provided a delivery device for the repair of cardiac function as suggested by Taylor, with an expandable filter, as taught by Jang, such that embolic material dislodged from the left ventricle is prevented from escaping.

11. Claims 31 and 63 are rejected under 35 U.S.C. 103(a) as being unpatentable over Taylor et al. (U.S. Pub. No. 2002/0169360) in view of Murphy et al. (U.S. Pub. No. 2004/0249408). Taylor discloses the invention as claimed, see rejection supra; however Taylor fails to disclose the expandable element having a plurality of support members. Murphy et al. (hereinafter Murphy) teaches a device and method for delivering a reinforcing element into a left ventricle. Regarding claims 31 and 63, Murphy teaches a series of ribs **214a-214d** composing the expandable element. These "support members" allow contraction to a stowed state, and expansion upon removal from an introduction device for expansion within the left ventricle ([0068]-[0072]). Therefore, at the time of the invention it would have been obvious to one having ordinary skill in the art to have provided an expandable element introduced within the left ventricle as taught by Taylor with a plurality of support arms as suggested by

Murphy in order to provide pressure to the ventricle in assisting the shaping of the left ventricle.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christine D. Hopkins whose telephone number is (571) 272-9058. The examiner can normally be reached on Monday-Friday, 7 a.m.-3:30 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Charles Marmor, II can be reached on (571) 272-4730. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information

system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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